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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|-------------------------------|------------------|
| 10/051,727 | 01/17/2002 | Rebanta Bandyopadhyay | LD0189 NP | 8647 |
| 23914 | 7590 | 08/11/2004 | EXAMINER | |
| STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000 | | | CHANNAVAJJALA, LAKSHMI SARADA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| DATE MAILED: 08/11/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,727

Applicant(s)

BANDYOPADHYAY ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13,15-17,19,22,25,28 and 30-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-7,9-13,30-32 and 34-54 is/are allowed.
- 6) ☐ Claim(s) 15-17,19,22,25,28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Amendments dated 12-23-03 and 3-31-04 are acknowledged.

Claims 30-54 are new. Claims 1-7, 9-13, 15-17, 19, 22, 25, 28 and 30-54 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 16, 17, 19, 22, 23, 25, 28 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,689,802. Although the conflicting claims are not identical, they are not patentably distinct from each other. Instant claims recite a pharmaceutical preparation comprising a lyophilized epothilone analogue and a solvent for reconstituting epothilone analogue, wherein the solvent and the compound are separated in different vials. Dependent claims recite the carriers and amounts of epothilone. Patented claims are directed to pharmaceutical compositions comprising a crystalline polymorph of an epothilone analogue together with carriers and diluents. Dependent claims of the patent are directed to methods of treating cancer or proliferative disorders comprising administering the composition containing Polymorphic crystalline form of epothilone analogue. Although instant claims differ from the patented claims

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in the form of the epothilone analogue i.e., lyophilized versus crystalline polymorph, the compositions in both sets of claims contain essentially the same compound dissolved in suitable solvents. Accordingly, once present in solution both sets of compositions do not exhibit substantial differences unless shown otherwise. Accordingly it would have been obvious for a skilled artisan at the time of the instant invention to prepare a composition of epothilone analogue comprising a crystalline or a lyophilized form, wherein the compound is dissolved in the solvent or separated until use and still achieve the same pharmacological effect.

Claims 15, 16, 17, 19, 22, 23, 25, 28 and 33 are directed to an invention not patentably distinct from claims 1-31 of commonly assigned US Patent No. 6,689,802. Specifically, the patent discloses and claims exactly the same compound as that claimed in instant invention. As explained, the instant claims differ from the patented claims in the form of the epothilone analogue i.e., lyophilized versus crystalline polymorph; the compositions in both sets of claims contain essentially the same compound dissolved in suitable solvents. Accordingly, once present in solution both sets of compositions do not exhibit substantial differences unless shown otherwise. Accordingly it would have been obvious for a skilled artisan at the time of the instant invention to prepare a composition of epothilone analogue comprising a crystalline or a lyophilized form, wherein the compound is dissolved in the solvent or separated until use and still achieve the same pharmacological effect.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned US 6,689,802, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under

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35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claims 15, 16, 17, 19, 22, 23, 25, 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,689,802 to DiMarco et al.

DiMarco et al teach the preparation of Polymorphic crystalline forms of epothilone analogues, pharmaceutical preparations containing the said analogues and method of treating cancer using the compositions. The epothilone analogues of DiMarco have the same structure as that claimed in the instant invention (col. 4). DiMarco suggests various dosages of epothilone analogues but not exactly the compositions containing separate vials of lyophilized compound and solvent and the specific carriers of the instant claims. However, the compositions in both sets of claims contain essentially the same compound dissolved in suitable solvents. Accordingly, once present in solution both sets of compositions do not exhibit substantial differences unless shown otherwise. Accordingly it would have been obvious for a skilled artisan at the time of the instant invention to prepare a composition of epothilone analogue comprising a crystalline or a

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lyophilized form, wherein the compound is dissolved in the solvent or separated until use and still achieve the same pharmacological effect.

Allowable Subject Matter

Claims 1-7, 9-13, 30-32 and 34-54 are allowed.

The following is an examiner's statement of reasons for allowance:

Instant claims are directed to a process of preparing an epothilone analogue comprising the steps of dissolving the specific analogue in a t-butanol and water solution, drying the solution under vacuum and performing a secondary drying to obtain a lyophilized product. The prior art of record generally teaches the step of lyophilization in the process of producing chemical compounds. However, the specific conditions of lyophilization of epothilone compounds would not have been obvious absent applicants' own disclosure of the epothilone compounds.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 30, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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